REMARKS

Claims 17-19, 27, 45-47 and 49-58 are pending herein. Support for these claims can be found throughout the specification and drawings. No new matter has been added.

The Examiner has rejected Claims 17-19, 27 and 45-47, 49 and 50 to a method of augmenting the nucleus of an intervertebral disc as presented in applicant's Response to Office Action including Amendment filed on August 21, 2008 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner maintains that the expression "remains essentially in place" in the amendatory recitation "while the implanted tissue remains essentially in place" in these claims constitutes new matter.

While applicants dispute the basis for the Examiner's contention regarding new matter, in order to advance the prosecution of the claims on the merits, applicants have amended Claim 27 to replace the recitation "the implanted tissue remains essentially in place" with "holding the second end of the length of natural tissue stationary". The latter recitation provides the essential step said by the Examiner to have been missing from the claim as originally presented (see page 2 of the Office Action dated April 22, 2008 where the Examiner asserts that the omitted essential step is "the step of holding the free end". Both this recitation and the deleted recitation are implicit from the disclosure of Figs 7-10 which show tissue implant 71 being introduced into disc nucleus space 78 employing cannula 76 with the implant thereafter being progressively bunched/folded by pulling on the free end of drawstring 73. One skilled in the art would readily understand from these drawings that second end 75 of implant

71 must be held stationary, e.g., by the surgeon, while drawstring 73 is being pulled in order to achieve the necessary bunching/folding action without such pulling of the drawstring resulting in the pulling of implant 71 out of disc nucleus space 78.

Applicants respectfully submit that there is no new matter in amended Claim 27 or in any of the claims dependent therefrom (i.e., remaining Claims 17-19, 45-47, 49 and 50) and that the supposed essential omitted step referred to by the Examiner in the Office Action of April 22, 2008 and in the present Office Action is now recited in these claims.

The Examiner has rejected Claims 51-53 and 56-58 to an intervertebral disc device as anticipated (35 U.S.C. § 102(a) and (e)) by Gabbay WO 02/39889 ("Gabbay").

In support of this rejection, the Examiner points to Fig. 4 which is characterized in the rejection as follows:

> ...Fig. 4 shows an intervertebral disc device having a length of natural tissue 48 with a "drawstring" 50 attached at or near its first end and passes through the tissue at a plurality of sites of at least three. Because the tissue is folded, the string extends through the tissue to or near the second end to keep together the folds and draw together the ends and can be said that it extends beyond the second end such that it can be secured or knotted such that the string does not become removed from the tissue. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The string is capable of being pulled. Regarding claim 52, Gabbay discloses natural tissue, page 9, lines 8-13. With respect to claim 53, Gabbay discloses pericardium tissue, page 8, lines 17, 18. Regarding claims 57, 58 it can be seen that the string passes through at least ten sites on the tissue.

Applicants respectfully submit that under no reasonable interpretation of the "drawstring" component of the intervertebral disc device of the rejected claims, and the

suture component 50 of prosthesis 46 of Gabbay (Fig. 4), can there be said to be the identity between these two structural elements that a proper rejection under 35 U.S.C. § 102 requires. A "drawstring", as it applies to applicants' claimed invention, is a string which is attached to an associated flexible structure, namely, to the first end of a length of natural tissue, and passing therethrough from one side to another at a multiplicity of sites along the length of the tissue such that upon being pulled causes the tissue within the intervertebral disc nucleus space to bunch up into one or more pleated folds, and ultimately, into a fully bunched, or folded, configuration. If a string is associated with some structure in such a way that it does not lend itself to being pulled or, if pulled, does not result in the bunching up of the associated structure into a pleated configuration, it is not a drawstring in the sense of applicants' claimed invention.

The suture 50 of Gabbay could be considered a "string" but it is most certainly not designed for being pulled much less to bring about the bunching up of prosthesis 46. Gabbay's suture 50 is not a drawstring; its function is to maintain layers 48 of prosthesis 46 attached to each other and, if desired, to be removed from prosthesis 46 so as to permit any portion of one or more layers 48 to be removed therefrom. Suture 50 in the Gabbay prosthesis functions much in the same way as stitching or basting (temporary stitching) in a garment, i.e., to join, or attach, separate parts of the garment together. Just as stitching or basting cannot reasonably be regarded as a "drawstring", so too suture 50 cannot be regarded as a "drawstring". There is nothing in the structure of Gabbay's suture 50 and its associated prosthesis 46 which even

remotely constitutes identity with the drawstring and its associated length of natural tissue comprising applicants' claimed intervertebral disc device.

The Examiner correctly states as a legal principle that an element adapted to perform a function is not a positive, i.e., structural limitation. However, the Examiner misapplies this principle in the case of applicants' drawstring.

Applicants' drawstring is a drawstring by virtue of its being secured at or near one end of a length of natural tissue and passing therethrough from one side to another at intervals along the length of the tissue to terminate in an end portion adapted to be pulled. Each of these necessary structural limitations of the drawstring and the manner of its attachment to its associated length of natural tissue are what make the drawstring a drawstring and not a suture or sutured device as in the case of the prosthesis of Gabbay (Fig. 4).

In view of the foregoing, the intervertebral disc device of Claims 51-53 and 56-58 is believed to be novel (and nonobvious) with respect to the disclosure of Gabbay.

The Examiner has rejected Claims 54 and 55 under 35 U.S.C. § 103(a) as unpatentable over Gabbay, discussed *supra*, in view of Sybert et al. 2002/0107570 ("Sybert et al.", issued as U.S. Patent No. 6,752,831).

Applicants maintain that at least some of the patentability of the device of dependent Claims 54 and 55 resides in those elements recited in independent Claim 51 discussed above, which elements are totally missing from Gabbay and, unquestionably, from Sybert et al. as well.

Accordingly, Claims 54 and 55 are directed to an intervertebral device which is nonobvious, and therefore patentable, over the combined device of Gabbay and Sybert et al. postulated by the Examiner.

The Examiner has rejected Claims 17, 18, 27, 45-47, 49 and 50 under 35 U.S.C. § 103(a) as unpatentable over Muhanna U.S. Patent No. 6,936,070 ("Muhanna") in view of Lambrecht et al. 2002/0151979 ("Lambrecht et al.", issued as U.S. Patent No. 7,258,700).

Of these claims, Claim 27 alone is in independent form with the remaining rejected claims, i.e., Claims 17, 18, 45-47, 47 and 50, depending therefrom. Addressing the specific evidentiary grounds of the rejection as the Examiner has applied them to Claim 27, applicants respectfully submit that nowhere in the combined disclosures of Muhanna and Lambrecht et al. can one reconstruct applicants' claimed method of implanting a length of natural tissue into an intervertebral disc nucleus space.

The Examiner refers to Muhanna Fig. 4B and Fig. 3A and the text of the specification relating to these two figures as supporting the conclusion that in combination with Lambrecht et al., all of the limitations of Claim 27 are met.

A close reading of the Muhanna disclosure reveals that little of applicants' claimed implantation method is to be found in this reference.

While Muhanna Figs. 3A and 4B and the related explanatory text do indeed disclose implanting a length of natural tissue (ribbon 16) within an intervertebral space, there is no disclosure or even the hint of a disclosure of the specific technique by which the accordion-like pleated folds of the implanted tissue shown in these figures

might be achieved. Muhanna merely discloses (specification, column 6, lines 37-40) that "...ribbon **16** may be inserted through a narrow incision **18** into the intervertebral disc **21** and the ribbon **16** confined therein by the residual intervertebral disc **21**." Nowhere in this disclosure or anywhere else in Muhanna is there the slightest suggestion of employing a drawstring technique to cause ribbon **16** to assume a pleated-folds configuration. What the Examiner refers to as a "drawstring" (element 15 of Muhanna Fig. 3A) is indicated therein to be a "fastener". A "fastener" is not a "drawstring" and a "drawstring" is not a "fastener".

The Examiner once again relies on Lambrecht et al., particularly Figs. 49G and 50F thereof, as evidence of the obviousness of applicants' claimed implantation method.

In their previous amendment, by way of patentably distinguishing Claim 27 over Lambrecht et al., applicants stated (pages 8 and 9 of their submission, emphasis in original):

> However, in order to advance the prosecution of the application, applicants have amended Claim 27 to expressly recite "a second, folded configuration having a multiplicity of <u>pleated</u> folds." The further recitation of "pleated" in amended Claim 27 precludes any reading of the claim on the implanted configurations disclosed in the Lambrecht et al drawings including the drawings cited by the examiner [among which are Figs. 49G and 50F] in support of the rejection.
>
> In addition to the foregoing recitation of the term "pleated," Claim 27 has been amended with regard to the structure of the intervertebral disc device being implanted. Amended Claim 27 now recites "an intervertebral disc device comprising a length of natural tissue... <u>and having a first end and second end</u>... said device additionally comprises a drawstring, <u>said drawstring being secured to the length of natural tissue at or near the first end thereof, said drawstring passing through the tissue from one side thereof to another at a multiplicity of sites at predetermined intervals along the</u>

length of the tissue, exiting the tissue at or near the second end thereof and extending beyond said second end to terminate in an end portion for pulling the drawstring."

In none of the devices disclosed in Lambrecht et al. is there any suggestion of an implant possessing a drawstring passing therethrough from one side to another at a multiplicity of sites at predetermined intervals along its length. Lacking this feature of applicants' implantable device (see especially Figs 9 and 10 of the subject specification in this regard), pulling on the Lambrecht et al drawstring [to use the Examiner's characterization of the structure indicated by reference numeral 406 of Fig. 49G] will not result in applicants' "second folded configuration having a multiplicity of pleated folds" but in the non-pleated configurations of the Lambrecht et al drawings referred to above.

In view of the foregoing amendments, Claims 17-19, 27 and 45-47 presented herein are believed to define invention which is patentable over Lambrecht et al.

These points of patentable distinctness over the Lambrecht et al. disclosure apply with equal force to the current rejection. Thus far, the Examiner has not responded to any of them. Paragraph 213 of Lambrecht et al. which the Examiner particularly relies on for the supposed teaching that control filament 406 functions as a drawstring fails to disclose several claimed limitations which are critical to the functioning of the drawstring in applicants' claimed method. Thus, paragraph 213 fails to disclose:

(1) that control filament 406 passes through a multiplicity of sites, in contrast to being secured to a multiplicity of sites,

(2) that control filament 406 passes through the tissue implant from one side thereof to another along the length of the tissue and

(3) that pulling on control filament 406 will result in a folded configuration of multiple pleated folds.

In conclusion, there is nothing in the combined disclosures of Muhanna and Lambrecht et al. which even vaguely resembles applicants' claimed method of implantation much less meet all of their limitations.

Claim 27, and Claims 17, 18, 45-47, 49 and 50 that dependent thereon, are therefore non-obvious, and therefore patentable, over Muhanna in combination with Lambrecht et al.

The Examiner has rejected Claim 19, which further limits the method of Claim 27 to one in which the natural tissue is small intestine submucosa, as unpatentable under 35 U.S.C. § 103(a) over Muhanna in view of Lambrecht et al. and further in view of Sybert et al. Since Claim 27 is patentable over all of these disclosures, individually or in combination, for the detailed reasons presented above, Claim 19 which depends therefrom is also patentable thereover.

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Reconsideration and allowance by the Examiner of claims 17-19, 27, 45-47 and 49-58 as presented herein are respectfully requested.

Respectfully submitted,

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